IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENUS LIFESCIENCES INC., Plaintiff, v. LANNETT COMPANY, INC., Defendant.	C.A. No. 1:20-cv-00770-LPS

REPLY BRIEF IN SUPPORT OF GENUS LIFESCIENCES INC.'S MOTION TO DISMISS COUNTERCLAIMS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

PRELIMINARY STATEMENT

Genus Lifesciences Inc. ("Genus") respectfully submits this Reply in support of its Motion to Dismiss Counterclaims filed by Defendant Lannett Company Inc. ("Lannett"). Genus sued Lannett for patent infringement on specific claims of three patents.[1] In response, Lannett filed counterclaims seeking to dramatically expand the scope of this case to adjudicate non-infringement and invalidity of unasserted claims and a discontinued product to which there is no real or immediate controversy. Genus has never asserted infringement as to those claims or that product and has no intention of doing so. Lannett only tries to attack these other patents and claims for an improper purpose: To create settlement leverage. Lannett even told Genus that unless Genus agreed to Lannett's settlement terms, it "would instead challenge the validity of Genus's patents." (D.I. 23 at 1.)

In Lannett's Opposition[2], Lannett presents no evidence of any affirmative acts by Genus to support Lannett's allegation that the Court has subject matter jurisdiction over the unasserted claims or the discontinued product. Nor could it. Lannett has not and cannot show that there is a live case or controversy to establish subject matter jurisdiction over the disputed counterclaims. Genus' Motion should be granted.

ARGUMENT

Subject matter jurisdiction does not automatically exist just because a competitor desires to mount a validity challenge to certain claims. *Streck, Inc. v. Research & Diagnostic Systems,*

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[1] Genus sued Lannett for inducement of infringements of claims 10, 20, and 26–28 of U.S. Patent No. 9,867,815 ("the '815 patent"); claims 1, 6, 9-11, 16, 19, and 20 of U.S. Patent No. 10,016,407 ("the '407 patent"); and claims 1, 4, 7–12, 15, and 18–20 of U.S. Patent No. 10,420,760 ("the '760 patent") (collectively, "the Asserted Patents" and "the Asserted Claims").

[2] Lannett's Memorandum of Law in Opposition to Genus's Motion to Dismiss is referred to as the "Opposition."

Inc., 665 F.3d 1269, 1283 (Fed. Cir. 2012). Instead, Lannett must show the existence of a live case or controversy at every stage of litigation. *Id*. Here, Lannett cannot, and does not. Lannett does not dispute that Genus never threatened to sue Lannett, never asserted infringement by Lannett, and never demanded a license or royalty related to Unasserted Claims, the Unasserted Patents, or C-Topical. (D.I. 23 at 3.) ("Genus has not yet overtly threatened to sue Lannett with respect to its as yet unasserted patents and patent claims. . . .") In the absence of facts supporting a live case or controversy, Lannett tries to portray Genus as a bad faith actor. Shorn of its rhetoric, Lannett's arguments reduce to a technical attack on Genus's covenant not to sue and an unreasonable and unjustified insistence of an "implied threat" based on Genus's legitimate complaints against Lannett on unrelated matters.

I. Genus' Covenant Not to Sue Lannett on the Unasserted Claims of the Patents-In-Suit Moots any Alleged Controversy.

Genus executed a covenant not to sue (the "Covenant") Lannett on claims 1–9, 11–18 of the '815 patent and claims 2–5, and 12–15 of the '407 patent, which are directed to the treatment of patients with hepatic impairment (collectively "the Unasserted Claims"). (D.I. 14-1.) The Covenant applies to Lannett's Numbrino product as "currently manufactured, marketed and sold on or before July 24, 2020." (*Id*. at 2.) This agreement, in which Genus unconditionally agrees not to sue Lannett for infringement based upon the product currently manufactured and sold by Lannett, eliminates any actual case or controversy as to the Unasserted Claims.[3]

There is a reason Genus has only asserted specific claims in this suit: Genus's Asserted

[3] *Super Sack Mfg. Corp. v. Chase Packaging Corp*., 57 F.3d 1054, 1056, 1059–60 (Fed. Cir. 1995) (*abrogation on other grounds recognized by Cat Tech LLC v. TubeMaster, Inc.* 528 F.3d 871, 879 (Fed. Cir. 2008) (statement that "Super Sack will unconditionally agree not to sue Chase for infringement as to any claim of the patents-in-suit based upon the products currently manufactured and sold by Chase . . . . completely eliminate[d] any actual case or controversy").

Claims and Unasserted Claims are directed to different subject matter. The Asserted Claims are directed to methods of administrating the claimed drug to a subject with *renal impairment* (D.I. 1 ¶¶ 14 (the '815 patent), 17 (the '407 patent)) or a patient *with an estimated glomerular filtration rate within a specified range* (*id*. at ¶ 20 (the '760 patent)). The Numbrino label provides specific instructions for administration to renally impaired patients, and therefore, Genus's complaint alleges that Lannett induces physicians to infringe the asserted claims.[4] In contrast, the Unasserted Claims recite methods of using cocaine hydrochloride in patients with *hepatic impairment*. (D.I. 1-1.)[5] Lannett's current Numbrino label instructs physicians to *avoid* using Numbrino on patients with hepatic impairment. (*Id*. at p. 178, § 8.6.) Thus, the Numbrino label, on its face, does not induce physicians to practice the methods of the Unasserted Claims.

If Lannett were to alter its Numbrino label in the future in a way that induces physicians to use Numbrino on patients with hepatic impairment, then Genus must be able to enforce its Asserted Patents against that future, hypothetical Numbrino product. The Covenant therefore specifically states the covenant applies unless Lannett's Numbrino label is "changed, amended, or modified in any way, and does not include any product wherein the Prescribing Information *eliminates either, or both, of the statement that 'It is not recommended to dose Numbrino in patients with hepatic impairment' and 'Numbrino should be avoided in patients with hepatic impairment.'*" (D.I. 14-1 (emphasis added)). Although Lannett falsely accuses Genus of holding back certain claims to sue Lannett in the future in its Opposition, whether Lannett infringes the Unasserted Claims in the

[4] For induced infringement, Lannett must have possessed "specific intent to encourage another's infringement." *Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304–05 (Fed. Cir. 2002). This specific intent is often shown through the sale of a product specifically labeled for the patented use. *See Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x. 917, 926 (Fed. Cir. 2011).

[5] A few of the Asserted Claims are directed to administering the solution to subjects with renal impairment *or* hepatic impairment.

future depends entirely on Lannett.

Lannett concedes that the Covenant covered Numbrino at the time it was first approved by the FDA, but posits a hyper-technical argument: Because Lannett made a few minor changes to its label since, the Covenant is ineffective. (D.I. 23 at 12, 13.) This is false. The minor, cosmetic change Lannett made to its label is not the type expressly contemplated by the Covenant—i.e. a material change regarding hepatically impaired patients that would implicate the Unasserted Claims. (*Compare* D.I. 24, Ex. 6 to D.I. 1-1.) There is no threat that Genus will accuse Lannett of infringing the Unasserted Claims in the future based on its cosmetic changes.[6]

Lannett cites *AstraZeneca LP v. Breath Ltd*., C.A. No. 08-1512, 2013 WL 2404167, *4 (D.N.J. May 31, 2013) for the proposition that for a covenant to be effective, it must cover all future versions of Numbrino. But *AstraZeneca* is inapposite. *AstraZeneca*, unlike here, is a Hatch-Waxman case in which AstraZeneca sued Breath on patents it later attempted to covenant. *Id*. at *2. The Court held it was "clear" that Breath "must either pursue arguably illegal behavior in launching its product or abandon its plan to launch." *Id*. at *4. Here, in contrast, Genus has never asserted infringement of the Unasserted Claims and Lannett has not alleged any fear that it is pursuing illegal behavior. It too knows that its label does not instruct physicians to administer Numbrino to hepatically impaired patients.

II. Lannett Fails to Establish Subject Matter Jurisdiction Over the Unasserted Patents.

In its motion to dismiss, Genus showed that there is no live case or controversy over the Unasserted Patents, because, for example, Genus has never alleged that Lannett infringes the

[6] Lannett's criticism of the Covenant is not even dispositive because, irrespective of the Covenant, subject matter jurisdiction cannot exist due to the fact that Lannett does not dispute that Genus has never accused Lannett of infringing the Unasserted Claims.

Unasserted Patents and settlement negotiations never specifically addressed these patents, or any specific patent for that matter. Lannett does not dispute these facts. Instead, Lannett posits three flawed arguments in an attempt to find subject matter jurisdiction over the Unasserted Patents.

First, Lannett alleges that during settlement negotiations of an unrelated false advertising case, Genus repeatedly demanded a royalty on all of Genus's patents. (D.I. 23 at 1.) That conclusory statement is not true, and lacks plausibility; the settlement correspondence factually contradicts Lannett's assertion. (D.I. 15, Ex. B.) In December 2019, when Lannett first asked for a royalty-free license to Genus's patents, Genus did not even have the information necessary to analyze infringement because Numbrino was not FDA approved. (*Id.*). Even after Lannett obtained FDA approval of Numbrino on January 10, 2020, certain information about its product was not publicly available. Lannett was the only party in the position to analyze whether Numbrino infringed, and Genus left it to Lannett to determine whether it desired a license.

Second, Lannett argues that the Unasserted Patents are part of the same family as the patents-in-suit and cover the same core technology. This is misleading at best. The Unasserted Patents cover materially different inventions—inventions that presently appear irrelevant to Lannett and Numbrino. For example, the '505 patent is directed to *naturally-derived cocaine hydrochloride* administered such that it results in a maximum plasma concentration C_{max} within a specified range. According to the label, Numbrino contains synthetically-made cocaine, not naturally-derived cocaine. Genus therefore did not assert infringement.[7]

[7] Genus is also not currently aware of any facts showing that Numbrino infringes any claims of the '843 and '961 patents. The '843 patent is directed to administering cocaine hydrochloride as a local anesthetic to *result in a range of absorptivity factors* in the patient. The '961 patent is directed to a specific 4% cocaine solution packaged in a particular container closures system provided that the cocaine is *greater than 3.4% by weight after storage over a certain time under certain conditions*.

Rather than address the subject matter of these irrelevant patents, Lannett attempts to manufacture a broad rule that a lawsuit over one patent creates subject matter jurisdiction over other patents involving the same family or technology. But the cases Lannett cites do not stand for this proposition. For example, in *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351 (Fed. Cir. 2013), the Federal Circuit found subject matter jurisdiction for declaratory judgment claims on related patents in the same family where there was "no question" that plaintiff's intended actions would "—in [defendant's] view—infringe the [related] patents." *Id*. at 1357–58.[8]

The actual rule is far more nuanced, as the Court explained in *Idenix Pharms., Inc. v. Gilead Sciences, Inc.*, No. 13-1987-LPS, 2014 U.S. Dist. LEXIS 118789, *8 (D. Del. Aug. 25, 2014) and requires a claim-by-claim analysis to determine whether a live case and controversy exists. In *Idenix,* Idenix sued Gilead for declaratory judgement that Gilead's planned sale of an HIV drug infringed Idenix's patents. *Id*. at *3. Gilead asserted counterclaims of non-infringement and invalidity over patents that were not asserted by Idenix, but part of the same patent family. *Id*. at *4. Idenix moved to dismiss Gilead's counterclaims, and in its analysis, the court noted that there were facts that weighed in favor of both sides of the issue. *Id*. at *9. In favor of jurisdiction was the fact that the parties were and had been engaged in patent litigation across the globe and that the patents were part of the same family and had a number of similarities. *Id*. at *9–10. Facts

[8] So too in *Nexans Inc. v. Belden Inc.*, 966 F. Supp. 2d 396, 402 (D. Del. 2013) (jurisdiction existed over an unasserted but "nearly identical" patent because the plaintiff claimed, in pre-suit discussions, that the defendant's products infringed each of a number of patents from the same family, even though only some of those patents were asserted in the litigation), *DNP Int'l Co. v. Natural Alternative Int'l Inc.*, No. 11-1283-GMS, 2013 WL 12221938, at *1 n.1 (D. Del. Feb. 27, 2013) (jurisdiction existed over a patent in the same family as asserted patents where declaratory judgment defendant conceded that the unasserted patents were "directed to the same invention."), and *Dror v. Kenu, Inc.*, No. 19-cv-03043-LB, 2019 WL 5684520, at *9 (N.D. Cal. Nov. 1, 2019) (jurisdiction existed as to two later-issued patents that had "similar claim elements" as two patents that the declaratory judgement defendant had expressly threatened to assert).

against jurisdiction included that Idenix had never sued, threatened to sue, or even discussed with Gilead the unasserted patents. *Id*. at *12–14. In addition, "noticeable differences" existed between the asserted and unasserted patents. *Id*. Ultimately, the court found that the differences between the claims of the asserted and unasserted patents coupled with the fact that Idenix had not sued, threatened to sue, or otherwise taken any clear and hostile action related to the unasserted patents defeated subject matter jurisdiction. *Id*. at *17. For the same reasons, the Court lacks subject matter jurisdiction here.

And third, Lannett incorrectly contends jurisdiction follows from the fact that Genus listed the Unasserted Patents in the Orange Book. But the specific patents Genus lists in the Orange Book are entirely irrelevant here because this is not a Hatch-Waxman lawsuit. Under the Hatch-Waxman Act, Genus is required to identify patents covering its Goprelto product (21 U.S.C. § 355(b)(1)), and the FDA publishes that patent information in the *Approved Drug Products With Therapeutic Equivalence Evaluations*, which is commonly referred to as the "Orange Book." 21 U.S.C. § 355(j)(7)(A). Under the Hatch-Waxman scheme, Genus's Orange Book listed patents are relevant to other drug applicants seeking to make a generic version of Genus's Goprelto. If an ANDA applicant, or a 505(b)(2) applicant, references Genus's Goprelto to obtain approval of its own version of Goprelto, then such applicant must submit a certification to all of Genus's Orange Book listed patents as part of it application, e.g., a Paragraph IV certification alleging non-infringement, invalidity, or unenforceability of the patent. 21 U.S.C. §§ 355(j)(2)(A)(vii), 355(b)(2)(A). In this case, however, Numbrino was approved pursuant to its own new drug application under 505(b)(2), not an ANDA, and Lannett's application contained no certifications

to any of Genus's Orange Book patents.[9] The current suit is a traditional infringement suit under § 271(b) based on Lannett actual sale of Numbrino, not a suit under § 271(e) based on Lannett's filing of a 505(b)(2) application.

Lannett attempts to analogize this case to a Hatch-Waxman case, *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007), but *Teva* is inapposite. There, Teva filed an ANDA with Paragraph IV Certifications to five Orange Book listed patents; Novartis sued Teva on only one patent under 35 U.S.C. § 271(e)(2); and Teva filed declaratory judgment counterclaims on the four remaining unasserted Orange Book patents "to obtain patent certainty." *Teva*, 482 F.3d at 1335. The "civil action to obtain patent certainty" is unique to the Hatch-Waxman Act and allows a Paragraph IV ANDA filer a right to bring a declaratory judgment action for non-infringement or invalidity of the listed patents against the patentee or NDA holder under limited circumstances including if the patentee does not sue the ANDA filer within 45 days. 21 U.S.C. § 355(j)(5)(C). Because of the Hatch-Waxman statutory scheme, if a patentee fails to sue an ANDA filer and the ANDA filer does not have the ability to "obtain patent certainty" then the patentee can "effectively extend[ ] the term of the [ ] patent." *Teva*, 482 F.3d at 1343. In fact, in *Teva*, the Court recognized that the "Congress intended this 'civil action' to adjudicate the very controversy Novartis has created here." *Id*. Unlike *Teva*, this is not a Hatch-Waxman case, there is no applicable "civil action to obtain patent certainty," Numbrino is already on the market, and Genus is not holding patents in reserve to delay Lannett's launch or extend the term of its patents.

Lannett also attempts to infer subject matter jurisdiction over the Unasserted Patents because Genus did not provide a covenant not to sue on those patents. (D.I. 23 (citing to *Arkema*,

[9] New drug applications can be filed under 505(b)(1), which includes full clinical reports demonstrating safety and efficacy, or under 505(b)(2), which includes abridged data demonstrating safety and efficacy and relies on published research on the drug product.

706 F.3d at 1358.) But there is no need. With respect to the Unasserted Patents, Genus has never threatened suit, never demanded a royalty, and never argued that any claim is infringed.[10] *Arkema* provides a useful contrast. There, the Court found an active controversy existed because there was "no question" that the plaintiff's intended conduct *would*, in the defendant's view, *indirectly infringe* its unasserted patents and yet the defendant refused covenant not to sue. *Id*. at 1358. Here, in contrast, these key facts are absent.

III. Lannett Fails to Establish Subject Matter Jurisdiction Over C-Topical.

Lannett's old, unapproved, and illegal C-Topical product is entirely irrelevant to this lawsuit.[11] It is undisputed that Genus has never accused, implied, or even suggested that Lannett's C-Topical product infringes Genus's patents. Lannett also does not dispute it discontinued the sale of C-Topical in 2019, has not sold it since, and cannot sell it in the future. Lannett, however, tries to fabricate a controversy where none exists by asserting that C-Topical and Numbrino are identical in composition, manufacturing process, packaging, and have been used by doctors in the same way. (D.I. 23 at 18.) This is false.[12] The FDA-approved Numbrino drug label is materially and substantially different from Lannett's unapproved C-Topical drug label as to the inventions

[10] The reason Genus provided the covenant not to sue the Unasserted Claims directed to administering the drug to hepatically impaired patients is because Genus did assert those patents against Lannett. By providing a claim-specific covenant not to sue, Genus eliminated any potential controversy with respect to the Unasserted Claims, thereby streamlining the lawsuit.

[11] Lannett takes issue with the illegality of C-Topical; but it was in fact illegally marketed. FDA assumes that an unapproved drug, like C-Topical, is illegal unless the manufacturer establishes the drug is grandfathered; Lannett asked the FDA to find that C-Topical was a legally marketed drug; and the FDA determined in 2015 that C-Topical is not legally marketed. Further confirming this fact, FDA has since taken enforcement action against Lannett to stop its sale of C-Topical. Just because FDA did not take earlier enforcement action to remove C-Topical from the market does not mean C-Topical was legally marketed.

[12] Lannett has sought its own patents for Numbrino, despite its prior sale of C-Topical, suggesting that Lannett understands the difference between the products.

claimed in the asserted claims of the patents-in-suit. (*Compare* D.I. 6-1 with D.I. 6-2 and D.I. 24, Ex. 6.) For example, the C-Topical label offers no instructions for use of the product on patients who are renally or hepatically impaired or over 65. (D.I. 6-1.) But the Numbrino label does. (D.I. 6-2 and D.I. 24, Ex. 6.) C-Topical is a different product with a materially different label for the purposes of the patent claims and Numbrino's infringement therefore is not dispositive, or even indicative, of any infringement by C-Topical.[13] As with the Unasserted Claims and the Unasserted Patents, Lannett has failed to meet its burden to show subject matter jurisdiction with respect to C-Topical. Lannett cannot point to any communications in which Genus has ever alleged it infringed, requested a royalty related to C-Topical, or threatened a patent infringement suit against C-Topical. There is no basis for any case or controversy related to whether C-Topical infringes Genus's patents and, therefore no subject matter jurisdiction.

CONCLUSION

For the foregoing reasons, Genus respectfully requests that the Court dismiss Lannett's counterclaims related to (1) claims 1–9, 11–18 of the '815 patent and claims 2–5, and 12–15 of the '407 patent, (2) the Unasserted Patents, and (3) C-Topical for lack of subject matter jurisdiction.

[13] Lannett submits case reports that purportedly show C-Topical being used in the same method as Numbrino, but these case report are unhelpful for Lannett. (D.I. 24, Ex. 7.) These reports do not show that Lannett is or was *inducing* infringement of Genus's patents with C-Topical because in the case reports, C-Topical was not even being used in renally or hepatically impaired patients or patients over 65.

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